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EXAMINER	
HAWES, PILI ASABI	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/964,273	BRYNJELSEN ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statement(s) filed 02-25-2003, 03-04-2003, 05-10-2004 is acknowledged. Claims 1-29 are pending in this action. Claims 1-29 are rejected.

Specification

The abstract of the disclosure is objected to because the particle size in the last sentence of the abstract is missing the correct particle size, 2 μm. The last part of the sentence reads: "particles size of less than about 2 m." Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "less than about" fails to particularly point out and distinctly claim the amount of organic phase the applicant intends to use as part of the instant invention.

Claims 1, 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "less than about" fails to particularly

point out and distinctly claim the particle size the applicant intends to yield from the method of the instant invention.

Claim 8 recites the limitation "method of claim 7" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 7 is directed to a process. It is suggested in the interest of maintaining consistency that either all claims be amended to recite a “process” or all claims be amended to recite a “method”. Amendment to the claims in this manner will obviate this rejection.

Claim 10 recites the limitation "method of claim 7" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 7 is directed to a process. It is suggested in the interest of maintaining consistency that either all claims be amended to recite a “process” or all claims be amended to recite a “method”. Amendment to the claims in this manner will obviate this rejection.

Claim 11 recites the limitation "method of claim 2" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 2 is directed to a process. It is suggested in the interest of maintaining consistency that either all claims be amended to recite a “process” or all claims be amended to recite a “method”. Amendment to the claims in this manner will obviate this rejection.

Claim 12 recites the limitation "method of claim 1" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 is directed to a process. It is suggested in the interest of maintaining consistency that either all claims be amended to recite a “process” or all claims be amended to recite a “method”. Amendment to the claims in this manner will obviate this rejection.

Claim 20 recites the limitation "method of claim 1" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 is directed to a process. It is suggested in the interest of maintaining consistency that either all claims be amended to recite a "process" or all claims be amended to recite a "method". Amendment to the claims in this manner will obviate this rejection.

Claim 23 recites the limitation "method of claim 1" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 is directed to a process. It is suggested in the interest of maintaining consistency that either all claims be amended to recite a "process" or all claims be amended to recite a "method". Amendment to the claims in this manner will obviate this rejection.

Claim 23 recites the limitation "method of claim 1, wherein the crude emulsion" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite a crude emulsion.

Claim 24 recites the limitation "method of claim 1" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 is directed to a process. It is suggested in the interest of maintaining consistency that either all claims be amended to recite a "process" or all claims be amended to recite a "method". Amendment to the claims in this manner will obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 11, 20-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai et al. US 5916596.

Desai teaches a method of preparing nanoparticles of pharmacologically active agents by solvent evaporation technique from an oil-in-water emulsion prepared under conditions of high shear forces, such as sonication, high pressure homogenation, etc. Employing albumin as the biologically surface active molecule (col. 5, lines 43-52).

The method comprises the steps of homogenizing a mixture of organic phase and aqueous phase (col. 7, lines 40-50). The organic phase contains a pharmaceutically active ingredient and the aqueous phase contains a biocompatible polymer (col. 7, lines 40-50). The biocompatible polymer is a mixture of the pharmaceutically active agent and albumin (col.8, lines 6-7). This teaching anticipates claims 7 and 11. The mixture is subjected to high shear conditions, such as sonication (col. 7, lines 40-50). This teaching anticipates claims 1-6.

Example 2 discloses a specific embodiment of the invention as claimed by applicant. The pharmaceutically active agent, paclitaxel is dissolved in a water immicible solvent, methylene chloride (col. 17, lines 20-21). Methylene chloride is a solvent with a vapor pressure higher than water. This teaching anticipates claims 20-22. A solution of albumin is added to the organic phase and the mixture is homogenized (col. 17, lines 21-24) and a crude emulsion is formed col. 17, line 25). The crude emulsion is sonicated in a 40kHz sonicator cell (col. 17, lines 25-26). This teaching anticipates claims 5 and 23. The solvent is evaporated and the particles are harvested with a

particle size of 350-420 nm (col. 17, lines 26-31). The example also discloses that the particles can be reconstituted to the original dispersion by adding water (col. 17, lines 35-36). This teaching anticipated claims 25-29.

The pharmaceutically active ingredients recited in claim 24 are anticipated by teaching of pharmaceutical active ingredients suitable for the process taught by Desai. The specific example of paclitaxel as the active ingredient anticipates claim 24 because paclitaxel is an antineoplastic.

Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Parikh et al. US 5922355.

Parikh discloses a method of preparing submicronized particles of poorly water soluble pharmaceutically active agents comprising reducing the particle size through sonication, homogenization, milling, micro fluidization and precipitation or recrystallization and precipitation of the compound using antisolvent and solvent precipitation techniques (col. 10, lines 23-29). The steps of the method comprise mixing the water insoluble pharmaceutically active ingredient, a phospholipid, with at least one nonionic, anionic, or cationic surfactant (col. 10, lines 30-34). This anticipates claim 6. Suitable surface active modifiers used in the invention are listed in column 3, lines 6-30). This disclosure anticipates claims 7-11 and 17-19.

Example 1 discloses a specific embodiment Parikh's invention, preparing microparticles of cyclosporine. Cyclosporine is added to mannitol (col. 4, lines 44-46). Mannitol is an organic compound and is an alcohol. This anticipates claims 20-22. To the organic phase is added egg phosphatidylcholine and a surface-active agent, Tween

(col. 4, lines 44-46). The mixture is homogenized and sonicated (col. 4, lines 50-56). A suspension of the particles was made in water (col. 5, 2-3). The particles sizes of the particles were in the range 337-361 nm (col. 5, lines 10-22). This teaching anticipates claims 1-8 and 12-16, 23, 25-29. Parikh lists types of water insoluble pharmaceutical compounds that would be suitable for this invention (col. 2, lines 52-64). This teaching anticipates claims 24.

Conclusion

Claims 1-29 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

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